



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,782	03/09/2004	George J. Brewer	4100.001099	1675

4743 7590 09/07/2006

MARSHALL, GERSTEIN & BORUN LLP  
233 S. WACKER DRIVE, SUITE 6300  
SEARS TOWER  
CHICAGO, IL 60606

EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/796,782

Applicant(s)

BREWER ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44,81-90,92-98,102-107 and 123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44,81-90,92-98,102-107 and 123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2006 has been entered.

Claims 80, 91, 99-101 and 108-122 are canceled. Claims 44, 81-83, 86, 87 and 93 have been amended. Claim 123 is newly added. Claims 44, 81-90, 92-98, 102-107 and 123 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration of Dr. Mazar, filed under 37 CFR 1.132, is acknowledged and addressed below.

***Claim Rejections - 35 USC § 112***

Claims 44, 81-90, 92-98, 102-107 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth in previous Office actions. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1623

Applicant's submission filed June 22, 2006 have been fully considered but they are not persuasive. In response to the rejection of record, Applicant has submitted a declaration by Dr. Andrew Mazar that purport to demonstrate that thiomolybdate compounds are enabled for the treatment of ocular neovascularization, rather than limited to the prevention.

The examiner agrees that Exhibit 2 demonstrates prevention but does not agree that the data, as presented in Exhibit 3, necessarily support a "trend towards regression of CNV." The fact that there is less CNV with the TM compounds than the control could be entirely due to inhibition of further CNV after the 14-day non-treatment period.

Exhibit 5 does appear to support regression. However, Applicant is reminded that the method must be enabled by the specification. The specification states that the therapeutic dosages for an average human male would be between 0.3 mg/kg and 3.0 mg/kg. See page 10, 1<sup>st</sup> full paragraph. However, the dosage used in the experiments from which the exhibit 5 data were taken is 50 mg/kg, an order of magnitude greater than the dosages contemplated in the specification. The examiner does not find the specification to be enabling when it would appear that it would require one of ordinary skill to make the leap from the dosages recommended in the specification to one over ten times greater than said dosages in order to see positive results.

Claims 44, 81-90, 92-98, 102-107 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Art Unit: 1623

The amendment to claim 44 adds a limitation requiring a “loading dosage of greater than 200 mg daily.” The examiner finds a discussion of loading dosages at the paragraph bridging pp 55-6. The specification discloses the range “greater than about 200 mg or so *up to the maximum dosages described herein.*” (Emphasis added.) The examiner does not find support for the range “greater than 200 mg.”

### ***Double Patenting***

Claims 44, 83-85, 104, 106, 107, and 116-122 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-48 and 57 of U.S. Patent No. 6,703,050, as set forth in the previous Office action.

Claim 44 has added the limitation requiring a loading dosage of greater than 200 mg. In carrying out the invention set forth in the claims, one of ordinary skill would look to the written description of the invention, including dosages outlined. Such loading dosages are disclosed at col 35, lines 10-35. It would have been obvious to one of ordinary skill to select a dosage set forth in the written description and arrive at the instant invention.

Applicant has previously indicated a willingness to file a terminal disclaimer if necessary upon a finding of allowable subject matter.

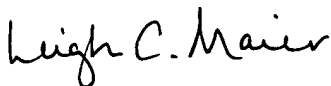
Art Unit: 1623

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



Leigh C. Maier  
Primary Examiner  
September 5, 2006